FDA/BPAC Meeting of March 15 and 16, 2001

**Blood Bags for Diversion of the Initial Collection**
**Mark Popovsky, MD; Haemonetics Corporation**

Ladies and gentlemen:

My name is Mark Popovsky, I am the Corporate Medical Director for Haemonetics Corporation. Thank you for giving industry the opportunity to speak on this topic today.

Haemonetics would like to comment on two aspects of this topic. First, Haemonetics' experiences to date with implementation of a pre-donation sampling pouch on all our currently marketed apheresis platelet and red blood cell sets. Secondly, our input on FDA's recommendation that the initial donor blood volume collected be diverted for all blood products collected.

Currently, all Haemonetics apheresis platelet and red blood cell kits have a sample pouch attached to a Y-connector on the donor needle [hold up disposable for audience to see].

We implemented the sample pouch on all our platelets sets back in the late 1980's. This implementation was driven by customer requests to provide a more user-friendly and easy method than a post-donation second venipuncture, to obtain donor blood samples to determine the donor's platelet count.
Limited studies were performed to investigate whether use of the pre-donation sample pouch had the added benefit of reducing the frequency of bacterial contamination observed. The results were inconclusive, and indicated that large numbers of collections will have to be tested for bacterial contamination before the benefit of diversion of the initial blood volume collected can be absolutely confirmed.

Our apheresis red blood cell sets have included a pre-donation sample pouch since early 1997. This implementation was in response to a concern that the saline compensation provided to the donor during the apheresis procedure could 'dilute' the donor's blood, potentially resulting in false negative results in the donor's infectious disease testing results when obtaining the donor blood sample post donation.
The feedback from blood centers that have implemented use of the pre-donation sample pouch on our apheresis sets has been very positive. Our customers use the sample pouch as intended; that is they obtain their donor blood samples pre-donation.
We recently worked with two major blood collection facilities to implement our apheresis red blood cell sets. Whole blood phlebotomists were primarily involved with this implementation, and 'conversion' of this staff from post-donation to pre-donation donor sampling was completed without major issues.

However, if the recommendation for pre-donation sampling is extended to all blood collections, Haemonetics foresees that there may be logistical issues to overcome when implementing use of the pre-donation sample pouch in mobile collection settings, for example, lack of access to handheld heat sealers or other sealing mechanisms used to hermetically seal the sample pouch.

Haemonetics has brought several examples of its pre-donation sample pouch and is more than willing to answer any questions from the BPAC members or the audience on the pre-donation sample pouch.

As you know, Haemonetics has served the blood collection industry for many years, and we actively support all efforts to enhance the safety, quality and availability of the nation's blood supply. We feel this experience, and our long experience with pre-donation sample pouches, qualifies us to give input on a proposed FDA recommendation.

We concur with FDA's belief that diversion of the initial blood volume collected in blood donations offers the potential to reduce the bacterial contamination of blood products, as suggested in two recent studies by Dr. Steven Wagner and by the French National Blood Agency. In addition, as a secondary benefit, the diversion of the initial blood volume may ensure adequate amounts of blood for donor qualification testing, thereby reducing the amounts of discarded blood products due to insufficient samples collected post-donation.

We believe, however, that a recommendation for diversion of the initial donor blood volume collected should be focused on platelet donations, rather than on **all** blood donations. The rate of bacterial contamination of platelets is approximately 1 in 2000 to 1 in 3000, whereas the rate of bacterial contamination in red blood cells is on the order of 1 in 40,000. Moreover, cultures of contaminated products have shown that the bacteria found in contaminated platelets are typical skin flora, while the bacteria found in contaminated red cells are indicative of a systemic infection in the blood donor.

Therefore, it is reasonable to conclude that implementation of diversion of the initial donor blood volume collected may indeed reduce the incidence of bacterial contamination of platelet products; but it is likely to have little or no effect on reducing the rate of red blood cell contamination. In addition, the cost to benefit ratio of adding a pre-donation sampling system for all whole blood and red blood cell donations may not be justified.

As part of any recommendations, FDA should clarify whether it is the intent to use the diversion of the initial blood volume for pre-donation testing. If this is the case we believe it raises some concerns regarding the type of systems used to withdraw the samples from a pre-donation volume and how to maintain a closed system. We believe that pre-donation sample collection systems should be designed such that the method of collection of the blood donor samples does not compromise the sterility of the collection system, i.e., the sampling technique and sealing mechanisms used should ensure a "closed system." If a guidance document results from the committee's recommendations, we suggest that FDA clarify this requirement in the guidance document.

Also, if FDA decides to move forward with a recommendation to implement systems for diversion the initial donor blood volume collected, FDA should allow blood collection device manufacturers to implement such systems per the *Least Burdensome Provisions* of the FDA Modernization Act of 1997. That is, those blood collection device manufacturers that do NOT seek to claim that the diversion of the initial donor blood volume collected reduces bacterial contamination should be able to implement their systems under a Special 510(k), NDA supplement, CBE30 or similar regulatory pathway. Additionally, blood collection centers should be able to add implementation of such systems to their Biologics License Applications through the Annual Reporting Mechanism. This would best serve to assure rapid and smooth adoption of this recommendation.

In conclusion, we believe that industry must strive to continuously improve the quality and safety of blood products. Haemonetics supports those regulatory initiatives which move us towards that goal.

Thank you for your attention.